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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/588,597

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EXAMINER

BABIC, CHRISTOPHER M

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/588,597	Applicant(s) MATSUHIRA ET AL.	
	Examiner CHRISTOPHER M. BABIC	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5-10,19 and 20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5-10,19 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 22, 2008 has been entered. Claim(s) 1, 3, and 5-10, 19, and 20 are pending.

Claim Rejections - 35 USC § 112 - Indefiniteness - New Grounds

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) Claim 2 recites the limitation "the nucleic acid exposing step" in line 2. There is insufficient antecedent basis for this limitation in the claim.

(b) Regarding claim 19, it is unclear if the term "thermal cyclers" is a required limitation of the claimed invention because the term is presented within parentheses.

Claim Rejections - 35 USC § 102 - Withdrawn

Applicant's amendments are sufficient to overcome the rejection of claims 1, 3, 9, 10, and 19 over Chu as well as the rejection of claims 1, 3, 5, 6, 9, 10, 19, and 20 over Blumenfield. Thus, the rejection has been withdrawn.

The rejection of claims 11-17 over Crouch is moot as the claims have been cancelled.

Claim Rejections - 35 USC § 102 - New Grounds

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 9, 10, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Hu (U.S. 5,939,251).

With regard to claims 1, 9 and 10, Hu teaches method of performing in situ PCR within a solid support having multiple compartments, wherein the cells are directly fixed on the solid support (fig. 3-6; col. 5-7, for example). Specifically, Hu teaches method comprising: fixing a cell-containing sample on divided compartments of a support (fig. 6; col. 5, lines 35-45; teaches fixing cells on the bottom wall (slide) of multiple defined

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compartments, for example); pre-treating the sample to enable amplification of nucleic acids contained in the sample (the teaching of in situ PCR necessarily means the cell sample was treated in some manner to allow amplification); performing PCR by placing a PCR mixture, containing primers for amplifying a target nucleic acid, into the compartments of the support (col. 6, lines 1-25; teaches providing PCR reagents to multiple compartments and thermal cycling, for example); determining whether amplified nucleic acids in a PCR solution contains contain the target nucleic acid (col. 6, lines 25-35; teaches further identification of amplified nucleic acids, for example).

With regard to claim 3, due to the lack a definite "exposing" step, the heat from the PCR is thought to encompass the limitation.

With regard to claim 19, Hu teaches the slide as able to fit within a thermal cycling apparatus (col. 6, lines 15-25, GeneAmp, for example)

Claim Rejections - 35 USC § 103 - New Grounds

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hu (U.S. 5,939,251) in view of Villepontueau et al. (U.S. 5,776,679).

The teachings of the previously applied reference(s) have been outlined in the above rejections. The previously applied reference(s) do not expressly teach the labeling of nucleic acids during PCR or detection of PCR products through electrophoresis.

With regard to claim 5, Villepontueau provides a supportive disclosure that teaches labeling nucleic acids during in situ PCR through the incorporation labeled nucleotides (col. 42, lines 50-65, for example). The reference highlights that labeled nucleotides prevent leakage of PCR products.

Thus, in summary, it is submitted that it would have been *prima facie* obvious to a skilled artisan at the time of invention to incorporate labeled nucleotides into in situ the PCR of Hu since the prior art expressly suggests such a modification to prevent leakage of PCR products.

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With regard to claim 20, the detection of PCR products through electrophoresis was well known as a standard method of PCR product detection. Villeponteau teaches such an electrophoresis method (col. 31, example 3, for example).

Thus, in summary, it is submitted that it would have been *prima facie* obvious to a skilled artisan at the time of invention to detect the PCR products of Hu by electrophoresis since the prior art recognized such a modification as standard within the art.

2. Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hu (U.S. 5,939,251) in view of Villeponteau et al. (U.S. 5,776,679) as applied to claim 5, and in further view of Stapleton et al (US 6,103,192).

The previously applied reference(s) do not expressly teach the detection of labeled PCR products through hybridization to immobilized probes in microarray format.

Stapleton provides a supportive disclosure that teaches a method wherein various biological specimens are collected, dried, transported, stored and processed on matrixes which adhere cells and viruses. The method involves fixing such samples to the matrixes, exposing the samples by heating them (col.17, lines 31-32, for example), applying the matrixes to thin-walled tubes for amplification (col. 17, lines 23-35; col.22, example 22, for example), and detection by either gel electrophoresis (col.17, lines 10-15; col.22, example 22, for example), or by applying the amplified product and detector probes to a probe array comprising capture oligonucleotides (col.16, lines 9-60; col.24,

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lines 21-50, example 7, for example). Furthermore, Stapleton states that such a detection system eliminates the need for gel electrophoresis, less amplification product is needed as the sensitivity of the detection increases, and allows for multiple oligonucleotide sequences at different array positions to be analyzed in the same detection reaction (col.16, lines 26-28, 57-59).

Thus, in summary, it is submitted that it would have been *prima facie* obvious to a skilled artisan at the time of invention to detect the PCR products of Hu through use of immobilized probes in a microarray format since the prior art expressly suggested such a modification to allow for the analysis of multiple sequences at once.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Babic whose telephone number is 571-272-8507. The examiner can normally be reached on Monday-Friday 7:00AM to 4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christopher M. Babic/
Patent Examiner
Art Unit 1637
Technology Center 1600